EXHIBIT 157

From: Hernandez, Tracey
Sent: Saturday, February 9, 2013 9:42 PM
To: Connell, Jill
Subject: DEA Compliance Initiatives Presentation
Attachments: DEA Compliance Initiative 2-9-2013.pptx

Jill-
I added the action items and the estimated completion. If Judy can put them in the Gantt Chart, it would be a big help. Again, the dates are estimates since input is needed from other departments to confirm. I'll add the inspection info tomorrow or early Monday.

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Qualitest Pharmaceuticals
120, 130 and 150 Vintage Drive
Huntsville, AL 35811
(256) 799-7178 (office)
[redacted] (cell)

#15

PAR-HERNANDEZ-015

From: Connell, Jill
Sent: Tuesday, February 19, 2013 11:06 AM
To: Hudson, Denise; Patel, Sanjay; Hernandez, Tracey; Bigelow, Peter; Smollen, Jon; Parker, Sandra; Richardson, Margaret
Subject: RE: DEA Compliance Update - SOMS
Attachments: SOMs_Overview_2_19_2013.pptx

Folks, <<...>>

Attached is the deck for today's meeting at 12:00 CT/1:00 ET.

Regards

jill

From: Connell, Jill
Sent: Tuesday, February 19, 2013 9:53 AM
To: Hudson, Denise; Patel, Sanjay; Hernandez, Tracey; Bigelow, Peter; Smollen, Jon; Parker, Sandra; Richardson, Margaret
Subject: DEA Compliance Update - SOMS

Folks, << File: Qualitest Final.pdf >>

Today's meeting at 12:00 CT/1:00 ET will be on our SOM's program.

Agenda:

- Overview of the Cegedim report on our SOM's program
  - Copy of report attached; **Redacted - Privileged Material**

Redacted - Privileged Material

- Review of DEA Compliance Group recommended next steps
- Discuss upcoming March 6th meeting with DEA

We will discuss the findings today but included below is a summary of the report.

Regards,

Jill

Summary of Cegedim report:

On January 16th and 17th, 2013 a review of our Suspicious Order Monitoring System was conducted by external consultants working for BuzzeoPDMA, a Cegedim Company and Richmond Analytics.

The auditors from these companies met with and gathered information from the following:

Aimee Cooper, Inside Sales Supervisor

Bambi McGaha, Customer Service Supervisor

Ricky Richardson, Systems Sr. Lead Programmer

Larry Shaffer, Sr. DEA Compliance Specialist

Jeremy Tatum, Director of Manufacturing Insights

Tracey was not able to participate due to an unannounced DEA inspection during the same timeframe but did provide information prior to this site visit via a telephone interview.

The consultants concluded that our "current SOM program, systems and procedures do not meet the regulatory requirements". Specifically, they recommended we make the following changes:

1. Increase the amount of initial due diligence to include on site meetings (audits) with customers to assure they have controls in place to safeguard against diversion and they have their own robust SOMS program (review of their SOPs and orders they themselves have reported to DEA).

- Visits should include both Corporate Offices and Distribution Centers and photographs should be taken and placed in the file along with copies of the customer's DEA and State registrations and copies of internet searches conducted (DEA website, NADDI, etc.).

2. Remove the Sales & Marketing and Customer Service functions from the SOM decision making process as conducting this review is "contrary to their primary mission of helping accounts with their current business and encouraging new business." The DEA Compliance Department is best suited for this purpose as "DEA Compliance personnel have a singular mission of protecting the firm from regulatory issues and should be assigned the primary role of conducting due diligence, evaluating pended or possibly suspicious orders, and clearing accounts or reporting the orders to DEA." The report goes on to say that procedures should be revised to include required communication between the groups, clear roles and responsibilities and procedures to escalate any disagreements.

3. Discontinue the use of thresholds and forecasts as part of the SOMs model. Retail thresholds "appear to be based upon perceived abuse potential and might be characterized as arbitrary."

- Wholesaler forecasts use the top 15 customers to develop projected purchases for all accounts and only flag if the customer orders 25% over the anticipated monthly quantity. The remaining 61 customers are grouped, in other words their orders would only be flagged if it put the entire group more than 25% above forecast. Therefore, the existing order management program used for wholesalers does not fulfill the SOMS requirements.

- All customer orders must be evaluated real time against quantity, frequency and pattern and compared to orders of others in the same class of trade.

4. Evaluate orders based on active ingredient quantity (mgs) rather than by dose count, within a specific product family. Also evaluate sales by grouping into zip code or geographical region to see if customers are purchasing more than the per capita norm. Utilize chargeback data to evaluate downstream distribution of our products.

5. System should be tested, validated and statistically defensible and must be dynamic to incorporate changing behavior and purchasing patterns.

6. Advised against providing customers the reason their orders are held or pended as this may result in customers working to avoid the one item that caused the order to be declined.

Produced In Native Format

SOMS Update

February 19 2013

endo

Agenda

- Overview of the Cegedim report on our SOM's program
- Review of DEA Compliance Group recommended next steps
- Discuss upcoming March 6th meeting with DEA

Overview of the Cegedim report on our SOM's program

E1052.9

- Overview of the Cegedim report on our SOM's program
  - On January 16th and 17th, 2013 a review of our Suspicious Order Monitoring System was conducted by external consultants working for BuzzeoPDMA, a Cegedim Company and Richmond Analytics.
  - Gathered information from the following:
    - Aimee Cooper, Inside Sales Supervisor
    - Bambi McGaha, Customer Service Supervisor
    - Ricky Richardson, Systems Sr. Lead Programmer
    - Larry Shaffer, Sr. DEA Compliance Specialist
    - Jeremy Tatum, Director of Manufacturing Insights
  - Note: Tracey was not able to participate due to an unannounced DEA inspection during the same timeframe

E1052.10

Cegedim Report Conclusion and Recommendations

- The consultants concluded that our "current SOM program, systems and procedures do not meet the regulatory requirements".
- Specifically, they recommended we make the following changes:
  - **Increase the amount of initial due diligence with customers**
    - To assure our Customers
      - Have controls in place to safeguard against diversion
      - Have their own robust SOMS program (review of their SOPs and orders they themselves have reported to DEA)
    - Our process should include:
      - On-site meetings (audits) for both Corporate Offices and Distribution Centers
  - **Remove the Sales & Marketing and Customer Service functions from the SOM decision making process**
    - The DEA Compliance Department is best suited for this purpose as "DEA Compliance personnel have a singular mission of protecting the firm from regulatory issues and should be assigned the primary role of conducting due diligence, evaluating pended or possibly suspicious orders, and clearing accounts or reporting the orders to DEA."

Cegedim Report Conclusion and Recommendations (cont.)

- **Discontinue the use of thresholds and forecasts as part of the SOMs model**
  - All customer orders must be evaluated real time against quantity, frequency and pattern and compared to orders of others in the same class of trade.
  - Retail thresholds "appear to be based upon perceived abuse potential and might be characterized as arbitrary."
  - Wholesaler forecasts use the top 15 customers to develop projected purchases for all accounts and only flag if the customer orders 25% over the anticipated monthly quantity.
    - The remaining 61 customers are grouped, in other words their orders would only be flagged if it put the entire group more than 25% above forecast. Therefore, the existing order management program used for wholesalers does not fulfill the SOMS requirements.

Cegedim Report Conclusion and Recommendations (cont.)

- **Evaluate orders based on active ingredient quantity (mgs) rather than by dose count, within a specific product family.**
  - Also evaluate sales by grouping into zip code or geographical region to see if customers are purchasing more than the per capita norm.
  - Utilize chargeback data to evaluate downstream distribution of our products.
- **System should be tested, validated and statistically defensible**
  - must be dynamic to incorporate changing behavior and purchasing patterns
- **Advised against providing customers the reason their orders are held or pended**
  - As this may result in customers working to avoid the one item that caused the order to be declined

DCT Recommends Phased Approach To Improvement Implementation: Phase I of III

– Phase I

- Execute and agreement with Cegedim in the next 60 days utilizing their SOMS solution
  - Begin to have Qualitest customer orders transmitted to Cegedim's validated system to review for suspicious orders.
    - System to include all class of trades/customers. (i.e. Wholesalers, Distributors, Manufactures, etc…)
    - System to include all controlled substances (Schedule II – V)
    - Calculation will use the last 12 months of shipping history. No arbitrarily set threshold or forecast based threshold
- Implementation resources
- Meet with the Sales, Marketing and Customer Service Departments to outline future roles, responsibilities and escalation procedures.
- Update SOMS SOP to reflect the new process.
- Review and lay out plans to integrate system requirements into SAP vs Cegedim
  - Include types of system simliar to Cegedim (above)
  - Log of customer contact in system; log should include release codes with common explanations with a call log for entering notes. Log will be able to be filtered, sorted, printed, and exported.
  - System evaluation will be based on dosage unit quantities. (For Tablets 1 Tablet = 1 Dosage Unit / For Liquids 5mL = 1 Dosage Unit)
  - System to show finished goods quantity ordered/shipped.
    - Backorders evaluated when product is ready to ship.
  - Excessive Quantity hold (OMS – Order Management System) must be released before SOMS evaluation and release.
  - Orders evaluated by Customer Service provide an unbiased review and allow for the application of "Know Your Customer" strategies.
  - System to allow for report generating capability.

Phased Approach To Improvement Implementation.

E1052.14

Phase II of III

- Phase II (incorporate higher level of evaluation complexity)
  - System to look at products containing listed chemicals (List I) – Pseudo.
  - System to evaluation of product mixes that are commonly abused together. (i.e. Hydrocodone + Q-Tapp [contains Pseudoephedrine])
  - System should differentiate between increase in future business and one time orders or temporary increases due to market shortages. System would need to be able to identify which increases are to be considered part of normal ordering pattern and which orders are one time or temporary increases. This would need to be done either when the order is entered or when it is flagged and reviewed and then released with code with appropriate definition. Definition selected would tell system how to calculate the increase. (Tie into release codes.)
  - System to show finished goods quantity ordered/shipped and how much API has been ordered/shipped to customer.
  - Failure rate. Reverse same criteria; how often do they go outside their normal pattern, frequency, and size.
  - Search/Trending should have default date range, with the ability to change criteria such as the date range, customer, and/or product/NDC.
  - Sales trending to assist with discovery of customer ordering pattern, frequency, and size. Include graphical representation.

Phased Approach To Improvement Implementation.

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Phase III of III

- **Phase III**
  - Onsite customer evaluations
  - Access to charge back data and 3rd party data (i.e. IMS). This provides visibility of product flow down customer stream and allows for enhanced compliance for the "Know Your Customer" requirement of DEA
    - Meet with Contracts Group (Stewart Williams) to determine how best to capture chargeback data for each customer.

Discuss upcoming March 6th meeting with DEA

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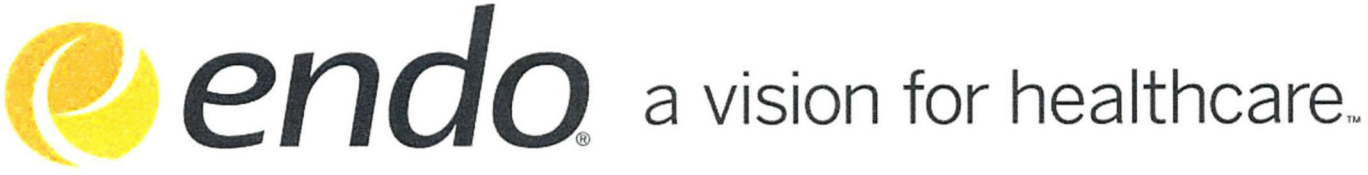
- DEA requested a meeting to discuss our controlled substance sales and our SOMS program
- Our expectation is that DEA will present our data to us in many ways
  - Customers (All)
  - Quantities as compared to other in same class of trade
  - Geographic location (state)
  - Product
  - Product mix
  - Specifically as they relate to Hydrocodone and Oxycodone
- We will be prepared to discuss our current SOMS program and phased approach of implementing improvements to our SOMS program
- We anticipate DEA will dictate changes to our program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